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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,321	10/26/2001	Liming Shao	SPV-045.01	1490

25181 7590 03/03/2003

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,321

Applicant(s)

Shao

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 and 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fentanyl in combination with a cyclodextrin, does not reasonably provide enablement for multitudes of compounds falling under the generic formula A in a variety of claimed carriers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.**

Formula A encompasses multitudes of compounds and instant specification fails to indicate whether the compounds falling under this formula are known in the art (other than fentanyl). If the compounds are applicant's invention, instant specification does not provide guidance to one of ordinary skill in the art as to how to prepare the claimed compounds. The only working example provided in the specification is that with fentanyl dissolved in a cyclodextrin while the claims are drawn to the generic formula A in combination with liposomes, cyclodextrins, micelle forming agents and polymeric carriers. It would require undue experimentation to prepare these compounds and find out which of

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these compounds have analgesic properties and find a suitable combination of the compound and the carrier. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to fentanyl in combination with a cyclodextrin disclosed as obtaining the claimed goal.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by

WO 92/02256 of record.

WO discloses cyclodextrin complexes containing fentanyl, alfentanil, sufentanil and lofentanil for the treatment of pain (note the abstract, Examples and claim 16).

5. Claims 1, 3-26 and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikhailova (XP 002208225) of record.

Mikhailova discloses liposomal formulations containing fentanyl for the treatment of pain in humans (note the abstract).

6. Claims 1, 3-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mezei (5,451,408) of record.

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Mezei discloses liposomal formulations containing fentanyl for the treatment of pain (abstract, Examples and claims).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Michailova or Mezei cited above.

Neither Michailova nor Mezei teach all of the claimed compounds falling under the basic structure of fentanyl. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to encapsulate any compound based on the basic structure of fentanyl in the liposomes of Michailova and Mezei with a reasonable expectation of success. Michailova and Mezei also do not teach the method of treating pain in claimed animals. However, in the absence of showing otherwise, it is reasonable to expect that the compositions which is effective in humans would be effective in animals since animal experiments are often extrapolated to humans.

9. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO cited above.

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WO does not teach all of the claimed compounds falling under the basic structure of fentanyl. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to encapsulate any compound based on the basic structure of fentanyl in the in the cyclodextrin compositions of WO with a reasonable expectation of success. WO also does not teach the method of treating pain in claimed animals. However, in the absence of showing otherwise, it is reasonable to expect that the compositions which are effective in rats would be effective in other animals and humans too.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility

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that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.


Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

February 25, 2003